

MAY 16 1997

K953647

510(k) Summary of Safety & Effectiveness

GENERAL INFORMATION: Sponsor: Meadox Medicals, Inc.
112 Bauer Drive
Oakland, NJ 07436

Contact Person: Stephen B Anderson

Submission Date: August 03, 1995

DEVICE INFORMATION: Generic Name: Balloon Dilatation Catheter

Trade Name: MS CLASSIQUE™ Balloon Dilatation Catheter
w/HYDROPASS™ Hydrophilic Coating

Classification Name: Cardiovascular - Percutaneous Catheter

PREDICATE DEVICE INFO: The following devices, to which substantial equivalence is claimed, serve as predicate devices for this premarket notification submission:

KIT	Proprietary Name	DATE
K942293	MS CLASSIQUE™ Balloon Dilatation Catheter	10/18/94
K943298	MS CLASSIQUE™ Balloon Dilatation Catheter	09/08/94

DEVICE DESCRIPTION: The MS CLASSIQUE™ Balloon Dilatation Catheter with HYDROPASS™ Hydrophilic Coating is a polymeric balloon mounted on a double lumen shaft, a design commonly referred to as a "Gruntzig style catheter". Proximally the product is fitted with a Y-connector system with two female luer fittings, one for passage of a guide wire, and the other for balloon inflation. The product is coated with Meadox's exclusive hydrophilic coating on the balloon, the tip and distal shaft.

BIOCOMPATIBILITY: Biocompatibility testing, conducted in accordance with the ISO-10993 standard, indicates that the MS CLASSIQUE™ Balloon Dilatation Catheter with HYDROPASS™ Hydrophilic Coating is safe for its labeled indications.

INDICATIONS: Indications for use have not changed, and are equivalent to those of the predicate devices cited above.

DESIGN MATERIALS: Design materials have not changed, and are equivalent to those of the predicate devices cited above.

MANUFACTURING: The manufacturing process now has an additional production step during which HYDROPASS™ Hydrophilic Coating is applied to the catheter.

SPECIFICATIONS: The package labeling of the MS CLASSIQUE™ Balloon Dilatation Catheter will now specify *Mean or Average Burst Pressure*. All MS CLASSIQUE™ Balloon Dilatation Catheters with HYDROPASS™ Hydrophilic Coating meet currently established performance specifications for uncoated MS CLASSIQUE™ Balloon Dilatation Catheters.

CONCLUSION: The addition of HYDROPASS™ Hydrophilic Coating to MS CLASSIQUE™ Balloon Dilatation Catheters does not alter the level of safety and effectiveness associated with the currently marketed products.